

ORGAN TRANSPLANTATION: THE DOCTOR'S DILEMMA AND THE LAWYER'S RESPONSIBILITY

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I. INTRODUCTION

On December 3, 1967, Dr. Christiaan N. Barnard, a South African surgeon made medical history at Groote Schuur Hospital in Capetown when he successfully replaced the damaged heart of 53 year old Louis Washlansky with that of a 25 year-old woman who died of brain injuries suffered in an automobile accident. Although Washlansky survived only eighteen days,¹ the magnitude of the feat (as well as later heart transplants) brought public attention to the medical profession and the possible role that organ transplantation may play in the future of mankind. The heart transplantation has brought to the surface many of the issues that were always present in transplantation but were not thought important enough to be raised to any great degree. The heart has been considered the traditional seat of life and its transplantation has aroused laymen, doctors, and lawyers to the point where they are constantly formulating new ethical, legal, medical, and moral problems. The purpose of this paper is to point out these problems and how lawyers may play a role in their solution. Lawyers have generally been considered the protector of the individual and have a professional responsibility to continue in that role.

Some of the problems presented and discussed herein are long term and therefore may be attacked methodically; others are short term problems that must be solved quickly in order that the future of transplantation is beneficial to mankind. This paper makes the general assumption that organ transplants, properly carried out, are beneficial to mankind in that they save lives. This in itself is reason enough to go to great expense to resolve the problems. In order to fulfill his professional responsibility the lawyer must strike a balance between two competing interests: (1) the medical profession which desires to perfect surgical procedures and which, in doing so, may become over zealous and cause transplants to be performed in situations where it is unnecessary and may actually waste lives; and (2) those individuals who are close to death and may be saved only by a transplantation which must be performed correctly to be of any benefit.

The legal profession, with its training in the decision making process, is the only group which can harmonize these competing interests in such a manner that the medical profession achieves its desired expertise in transplantation surgery while the lay public remains free of any fear about be-

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¹ THE AMERICAN ANNUAL 1968, at 606; Time Magazine, December 15, 1968, at 64.

ing an experimental guinea pig. The problem is not easy, however, and the lawyer will have to concern himself with the long range effects of transplantation if he is to be successful.

The problems to be considered include the following: (1) who may be a donor; (2) may a minor donate his organs; (3) what constitutes informed consent; (4) what is the definition of death; (5) who determines death; (6) may gifts of organs be revoked; (7) what are the rights of next-of-kin at death; (8) how are gifts of organs made; (9) may donors receive payment for their organs; (10) should treating physicians be allowed to participate in the transplantation of their patients' organs; (11) what controls should be placed on physicians; (12) if there is a limited supply of donated organs, who is the recipient; (13) who chooses this recipient; and (14) what criteria are used in determining the donor. These are just a few of the problems involved. It should be observed that the problems are legal, medical, moral, and ethical and this prevents any easy solution. However, the lawyer has his responsibility and especially so when the problems are difficult.

After a brief look into the medical aspects of organ transplantation, the individual problems and their solutions, or means to solution will be discussed individually. Initially the several kinds of donors will be discussed and the problems and possible solutions each type presents. The recipients and the classes that may develop are then presented along with their attendant problems and possible solutions.

II. MEDICAL BACKGROUND

In order to fully comprehend the legal and moral issues involved in tissue transplantation, it is necessary to understand the medical parameters. This writer has a fairly comprehensive understanding of the medical procedure involved in performing a kidney transplant; and, as kidney transplants present problems typical of all transplant procedures, they will be used as the model for discussion.

Transplantation of tissues is not a new medical technique. Skin grafts outdate the birth of Christ and human blood transfusions have been performed for over one hundred-fifty years. Transplants of the cornea, with which non-medical personnel are generally familiar, are also of long standing.² In 1954 at the Peter Bent Brigham Hospital in Boston, Massachusetts, Dr. Joseph Murray performed the first successful kidney transplantation when he transplanted a healthy kidney from an adult male to his identical twin brother.³ It was at this time that tissue transplantation came of age and achieved a permanent place in the medical world. Prior to that time physicians and surgeons believed that the operation could be

² Stason, *The Uniform Anatomical Gift Act*, 23 BUS. LAW. 919 (1968).

³ CALNE, *RENAL TRANSPLANTATION* 21 (1967).

performed but were always confronted by the rejection mechanism in non-identical twin recipients. This transplantation was made possible by the earlier work of Alexis Carrel who had perfected the necessary surgical techniques in animals⁴ and William J. Kolff who had constructed the first artificial kidney in the Netherlands in 1943.⁵ Kolff's artificial kidney has been greatly improved upon and modified by the staff at Peter Bent Brigham Hospital⁶ and plays an important part in keeping a transplant patient alive until a suitable donor can be found to provide a kidney.

The kidneys function in removing the waste products that result from bodily metabolism and maintain the body's salt and water balance. An accumulation of waste products (uremia) results when the kidneys are unable to function because of a disease such as glomerulonephritis or pyelonephritis. As a result there is a poisoning of the blood and the patient dies if medical aid is not available. Medical aid is either hemodialysis by means of Kolff's artificial kidney or peritoneal dialysis. In the artificial kidney blood is passed through a long cellophane tube bathed in a dialyzing solution and back into an artery. The cellophane tube, a semipermeable membrane, acts like the tissue layer in the kidney which serves as a filter. The dialyzing solution is lower in concentration than the blood so low molecular weight waste products diffuse through the cellophane into the dialyzing solution. By this process the waste products in the blood may be removed over a period of six to ten hours.⁷ In 1966 the process of peritoneal dialysis was introduced into the medical practice. In this process the peritoneum of the kidney patient is the semi-permeable membrane. The patient's abdomen is punctured immediately below the umbilicus and a plastic catheter is inserted. The dialyzing solution, in two liter quantities, is then pumped into the patient by gravity flow, at which time the flow is reversed with the dialyzing solution flowing back out containing those waste products which crossed the peritoneum due to the differing concentrations. This process takes anywhere from eight to sixteen hours, depending on how many liters are pumped into the patient and how well the procedure works for that particular patient.

The procedure leading up to the transplant is simple and uniform throughout the country. The patient enters a large hospital (generally large teaching hospitals are the only ones that do dialysis and organ transplants) with a fatal renal disease. The artificial kidney or peritoneal dialysis is used in one of two ways: it either supplements the actual work of the kidney thereby allowing them to rest and make repairs or it

⁴ Carrel, *The Preservation of Tissues and its Application in Surgery*, 59 J.A.M.A. 523 (1912).

⁵ BRITANNICA, BOOK OF THE YEAR 1967, 529.

⁶ MOORE, GIVE AND TAKE: THE DEVELOPMENT OF TISSUE TRANSPLANTATION 56 (1964) [hereinafter cited as MOORE].

⁷ BRITANNICA, *supra* note 5, at 529.

carries on all the kidney functions until a suitable donor can be found. Often times the patient suffering chronic renal disease is dialyzed several times and then is allowed to return home and report to the hospital only once or twice a week for treatments until a donor is found.

Finding a donor is one of the greatest problems the chronic renal patient (and the physician) is faced with. There are two reasons for this. Generally people are not overly anxious to part with their organs and those who are must satisfy certain immunological criteria. When any foreign body or substance is injected or placed in a human being a rejection mechanism commences. That is, a human's lymphocytes begin to attack any substance which it does not recognize as itself. There are degrees of rejection depending on how great the tissues differ from each other immunologically. This difference, which is non-existent in identical twins because they develop from the same fertilized egg, is measured by means of a histocompatibility test and is somewhat analogous to blood typing. Generally, the closer two people are genetically the more probable it is that their tissues will be compatible and thus one may serve as a donor for the other.

Once a compatible donor has been found and the appropriate consent obtained the surgical procedure begins. This procedure is generally the same in most hospitals. The donor (regardless of whether he is alive or has expired) and the recipient are placed in adjoining operating rooms. The recipient is prepared⁸ to receive the new kidney while the donor undergoes a nephrectomy (removal of the kidney). The kidney is then transferred from one operating room to the other where it is surgically implanted into the recipient who is then removed to the intensive care unit for close observation and a period of convalescence.

In addition to the surgeon's ability and technique the most important factors of the operation are the time the operation consumes and the temperature of the kidney being transplanted. The critical time in organ transplantation is the ischemic interval which is the period of time beginning when circulation of blood to the donor's kidney is cut off in the donor until it is reestablished in the recipient. The critical temperature is the temperature of the tissue being transplanted during the ischemic interval.⁹ The critical nature of these factors is not difficult to understand. The various cells of the body succumb to a lack of oxygen (anoxemia) at different rates. This distinction is irreversible and increases as the critical time and temperature increase. Kidneys which have been removed without cooling can be transplanted successfully if the time interval is one hour or less. A tissue transplant is considered successful if it will carry out its

⁸ Some recipients have their diseased kidneys removed before the transplant, some at the time of the transplant and in some the diseased kidneys remain in the donor and are joined by the transplanted kidney.

⁹ MOORE, at 135.

normal cellular functions upon implantation into its new host with a resumed arterial oxygen supply.

The critical temperature for most tissues appears to be around 25°C. Below this temperature, many organs can be kept alive for several hours without blood flow. If the temperature is reduced to 15°C, or lower to the freezing point, additional preservation is gained, but there are some problems of damage to tissues, particularly if freezing is produced and the cells swell and break.¹⁰

As an aid in preserving organs for short periods of time there has been developed a hyperbaric organ preservation chamber. This apparatus consists of a chamber into which the nephrectomized kidney is placed. The kidney is then perfused with a 5 to 8° C, 5 percent low molecular weight dextran solution under hyperbaric conditions of three atmospheres pressure.¹¹ By means of this method a human kidney was successfully stored for eight hours.¹²

The liver, the heart, and the lungs have also been the subject of attempted organ transplants. Their critical time is ten to fifteen minutes. While that of the brain, which has not as yet been transplanted, is three to six minutes, at which time "there is absolute cessation of brain function, reflexes cease, the pupils become widely dilated [and] the electroencephalogram [a record of the electrical activity of the brain] shows no activity."¹³ It will be shown that the present time limitations imposed upon the transplant surgeon result in several severe legal questions.

Immunological rejection is the process by which the lymphocytes of the body fight off all foreign tissue which it does not recognize as "self." There have been numerous efforts to suppress this rejection mechanism. The first attempt was whole body irradiation which was a destruction of the antibody producing cells. The main problem with this method was that the dose of irradiation could not be correctly calculated. If too much irradiation was given, the tissue graft would be successful but the body's defenses would be lowered to such an extent that the patient would die from infections it received after implantation and was unable to fight off. On the other hand, if the dosage was not at a sufficiently high level, the bodily defenses were not suppressed enough to prevent the lymphocytes from attacking the transplanted organ. The delicate balance required could not be achieved.¹⁴ The present means of suppression is by the use of antilymphocyte-Globulin—commonly referred to as ALG. This substance interferes with the lymphocytes which cause rejection. It is used in con-

¹⁰ MOORE, at 135, 136.

¹¹ FEEHSTER, *IN VITRO* PRESERVATION WITH INTERMITTENT LOW FLOW HYPERBORIC, HYPOTHERMIC PERFUSION.

¹² Manax, *Hypothermia and Hyperbaria*, 192 J.A.M.A. 755 (1965).

¹³ MOORE, at 132.

¹⁴ MOORE, at 81, 82.

nection with two standard drugs—Imuran and Prednisone.¹⁵ ALG is prepared by injecting human lymphocytes into horses which then produce antibodies to the lymphocytes. This antibody is then extracted from the horse's serum and injected into the transplant patient where it interferes with the production of lymphocytes to attack the newly implanted foreign tissue. ALG seems to work although there have been allergic reactions in patients as a result of a human reaction with some of the components of the horse serum. This procedure is still in the experimental stage, however, and experiments are being conducted as to how and when ALG injections should be given and if and when they may be discontinued.

III. DONORS

Once the medical parameters of kidney transplantation are understood, it is possible to consider the legal and moral complications which affect the doctor, recipient, donor, and lawyer. The legal problems, which often necessarily include moral considerations, initially deal with the donor. The problem of informed consent places a tremendous burden on the physician. He must confer with the potential donor; advise him of the pain and suffering he may have to endure; discuss the possibility of unknown long term complications resulting from a nephrectomy; inform him that the procedures are still experimental and his gift may be for nothing if the recipient dies; and relate to him the possibility of psychological trauma as a result of losing a part of his body and not knowing if it was worth it all. Each type of donor presents different problems, different challenges and different solutions. For that reason the donors will be discussed according to the particular type.

A. The Live Adult Donor

To date the most common, as well as most successful donor has been the adult donor who is alive, healthy and a close relative of the recipient. As explained above, the closer the donor and recipient are genetically, the fewer immunological barriers that are likely to be encountered and the greater the chances are that the transplant will succeed. In obtaining the informed consent of the patient the physicians and surgeons have two objectives. First, they want to be certain that the potential donor is fully aware of the possible consequences and repercussions of his donation and gives his consent nonetheless. Second, as a result of such informed consent, the doctors involved in the transplantation are thereby protected from any assault or battery actions which might be brought.

In a New York case in which the plaintiff was admitted to the hospital suffering from a stomach disorder and a fibroid tumor was surgically

¹⁵ N.Y. Times, Sept. 11, 1968, at 8.

removed while she was under the effects of ether and without having consented to such removal the court held

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.¹⁶

In a case in which the plaintiff was referred to a surgeon who diagnosed his case as arteriosclerosis, the plaintiff brought a malpractice action because of the resulting paralysis of his legs. The court stated

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise, the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. At the same time, the physician must place the welfare of his patient above all else and this very fact places him in a position in which he sometimes must choose between two alternative courses of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; this may well result in alarming a patient who is already unduly apprehensive and who as a result refuse to undertake surgery in which there is in fact a minimal risk; it may also result in actually increasing the risks by reason of the physiological results of the apprehension itself. The other is to recognize that each patient presents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to informed consent.¹⁷

A minor was suffering from "spells" and a neurologist subjected the boy to an arteriogram (a dangerous procedure in which three percentum of the cases result in death, paralysis or other injurious outcome) which resulted in partial paralysis to the youth. The court stated

Unless a person who gives consent to an operation knows its dangers and the degree of danger, a "consent" does not represent a choice and is ineffectual.¹⁸

With these cases in mind, two problems are created for the surgeon. The first is how well a potential donor can understand the medical terminology the surgeon uses in explaining the operation, and the possible consequences thereof, to him. Although a donor may understand the literal meaning of the phrases "pain and suffering" and "experimental procedure" it is probably the case that he does not adequately comprehend

¹⁶ *Schloendorff v. The Society of the New York Hospital*, 221 N.Y. 125, 129-30, 105 N.E. 92 (1914).

¹⁷ *Salgo v. Leland Stanford, Jr. University Board of Trustees*, 154 Cal. App.2d 560, 578, 317 P.2d 170 (1957).

¹⁸ *Bowers v. Talmage*, 159 So.2d 888, 889 (Fla. 1964).

the scope and meaning of the words as they are used in a medical context. The second difficulty is that the surgeon may not be able to give the potential donor what is commonly referred to as the "straight story." At the present time organ transplantation is still a relatively new and experimental field in which the long range effects have not as yet been studied. In the case of the kidney there seems to be little evidence to indicate that any serious malfunctions result. However, fifteen years [since the first kidney transplant was successfully performed on December 23, 1954, in Peter Bent Brigham Hospital by Dr. Joseph E. Murray,¹⁹ is not long enough to conclusively show that such malfunctions do not exist—especially when the donors have all been young and physically fit at the time of the donation.

One major difficulty should be considered. In the human body there are two kidneys. If one is injured the second carries on the entire metabolic function of both kidneys with no resultant harm to the individual. However, if a donor, who is left with only one kidney, subsequently suffers damage to his remaining kidney, he is in the same position as the recipient of his kidney and is a candidate for transplant himself. Thus, there is a definite danger in giving a kidney and the donor must be so advised.

Other problems are also present. Transplantation is experimental and the doctors have some self-interest in performing the surgery. Promotions, national acclaim, higher salaries and medical data are the results of successful organ transplantation. With these in mind the surgeon may be tempted to minimize any side effects which he feels might cause the donor unwarranted consternation. At this point the physician has made a value judgment that the small possibility of harm to be incurred by the donor is outweighed by the potential benefit to science, the recipient and, possibly, the physician himself. In this situation the donor should have an absolute right to refuse donation for *any* reason he might have, however trivial or misinformed it might be, because he will not benefit at all from the donation. The doctor *must* make a full disclosure of *all* the risks involved in order that the lay public maintain its respect for the medical profession.

It is very conceivable that the courts would hold the doctor to such a high standard where a donor is involved. Unlike the case where some good results from a surgical procedure, the doctor here does not have to balance the benefits to the donor against the harm and then decide what to tell him—there are no physical benefits. The medical profession should *adopt* such a position. In this way the experiments will be conducted on willing subjects, public confidence in physicians will continue, and, as a result more people will be willing to donate their organs.

¹⁹ MOORE, at 73.

Another difficulty is the extent to which the surgeon or hospital may be legally liable to the donor after the donation in case some serious malfunction should occur. The doctor is responsible for good surgical procedure and proper patient care. That is, the doctor is under no legal obligation to care for the donor at his (the doctor's) expense or to see to it that the hospital provides free peritoneal or hemodialysis and nursing care should the donor develop chronic renal disease after the donation. The donor willingly gives his informed consent and as a result suffers the consequences which result from any risks he has assumed.

A look at several consent forms currently in use indicates several ways in which the doctors have attempted to comply with the legal requirements of willing, informed consent. The Ohio State University Hospitals use a form entitled "Authorization for Donation to a Named Beneficiary of a Human Organ or Part by a Living Donor".²⁰ As the title indicates,

²⁰ **AUTHORIZATION FOR DONATION TO A NAMED RECIPIENT
OF A HUMAN ORGAN OR PART BY A LIVING DONOR.**

I, _____, of _____,
name of donor street address

_____, do hereby evidence my consent to donate
city state

to _____ an organ or part from my body, namely,
name of recipient

_____, to be transplanted into the body of _____
item name of recipient

I further consent to and authorize the Ohio State University through its College of Medicine and the physicians and surgeons designated by and acting for it to perform the necessary operational procedure to accomplish the removal of said _____ from my body. I hereby certify that I have had explained to my satisfaction by one or more of said physicians and surgeons the operational procedure necessary for the accomplishment of my donation and the consequences to me thereof and of such donation.

I further certify that I am over the age of 21 years and that I am unmarried* married* and that the name of my spouse is _____.

Dated: _____ Time _____ am* pm*

_____, witness

_____, donor

_____, witness

The undersigned being the wife* husband* of the above _____
name of donor

does hereby certify that _____ he had read and understands the above statement made and consent given by said _____ and that the consequences

_____ name of donor
to _____ of the operation and removal of the

_____ name of donor
_____ have been satisfactorily explained to the

_____ organ or part to be removed
undersigned who consents to such operation and removal for the purpose of trans-

planting the _____ into the body of _____
organ or part to be removed name of recipient

Dated _____ Time _____ am* pm* _____
witness

_____ wife* husband* of _____
name of donor witness

* strike part not applicable

have obligations.²² Thus a physician should realize that informed consent is not the only matter to be considered and should not allow people to donate when he suspects that their social and economic positions might not withstand a future loss which the death of the donor might produce. To impose such an obligation on a physician places him in a very difficult position. He is not qualified to make such evaluations because his education and clinical experience have not trained him to do so.

The lawyer has a responsibility to fulfill in this area. Legislation could be enacted to promote a social worker-type investigation into each donor's background. This social worker would investigate, report back to the surgeon who is to perform the transplant and recommend allowing the person to donate or not. There could be a presumption in favor of donating and the surgeon would be morally bound to follow the recommendations in the social worker's report. Such a presumption should be contained in the state statutes. An alternative might be a legislative requirement that the social worker's findings and recommendations be communicated to the donor so that a truly informed consent would be given.

The social worker need not be a genuine antagonist to the surgeon and the hospital as long as he (or she) is a professional in the field as a result of training at a university and a degree in social work. Having received this training the social worker could be employed by the hospital and still be effective in the position.

B. Live Minors as Donors

Just as there are problems with adults as donors for organ transplants, even greater problems exist when a minor is the donor. The consent of the parents of a minor must be obtained before a minor may be operated on. There must also be some benefit to the minor.²³ In the discussion about live adult donors it was pointed out that finding that a surgical removal of a kidney has benefited the donor is almost impossible. Indeed the opposite is generally the case in that the donor is placed in a position of risk for the remainder of his life. Although an adult may consent to such an operation, a parent may not consent to such a non-beneficial operation on his child.

This problem arose in 1957 in the Supreme Judicial Court of Massachusetts in a case involving identical twins. Maggie Masden and her nineteen year old twin sons, Leon and Leonard, were the plaintiffs in a declaratory judgment action against surgeons on the staff of the Peter Bent Brigham Hospital in Boston, Massachusetts. Leon was suffering from chronic glomerulonephritis, a fatal kidney disease from which he

²² Martin, Arnold, Zimmerman, and Richart, *Human Subjects in Clinical Research*, 279 NEW ENG. J. MEDICINE 1426 (1968).

²³ *Bonner v. Moran*, 126 F.2d 121 (D. C. Cir. 1941).

would die without transplantation. Leonard, on the other hand, was in perfect health. After diagnosis at the Brigham Hospital the defendants agreed to perform a kidney transplant operation and the three Masdens (the father had previously deserted the family) who had come to Boston solely for purposes of the transplant, gave their consent to such an operation. The surgeons and the Hospital acting on the advice of counsel that they might be subject to civil liability and criminal prosecution decided not to proceed with the transplant. Thereupon plaintiffs filed their declaratory judgment action.²⁴

Apparently the hospital and surgeons were worried about the lack of benefit to the minor donor. Therefore they produced the testimony of a psychiatrist whose statements led the court to conclude that:

if this operation is not performed and Leon dies in his opinion [the psychiatrist's] a grave emotional impact on Leonard would result. This would be further aggravated by a realization that it was within his power to have saved the life of his brother had this operation been performed.²⁵

The court also found

Leonard has been fully informed and understands the nature of the operation and its possible consequences.²⁶

The court then ruled

. . . as a matter of law that it is proper for the defendants with the assistance of . . . Peter Bent Brigham Hospital, its agents and servants, to perform the operation herein described with the consent of all the plaintiffs without incurring any civil liability to Leonard or any criminal prosecution.²⁷

This case was decided on June 12, 1957. On August 30, 1957, and November 20, 1957, in almost identical cases the same result was handed down by this same Massachusetts Supreme Judicial Court. The cases of *Huskey v. Harrison*, No. 68666 Eq. and *Foster v. Harrison*, No. 68674 Eq. were declaratory judgment actions dealing with the transplantation of kidneys in fourteen-year-old twins. In both cases *Masden* was cited as controlling and in both cases identical results were handed down even though different judges were sitting in each action. These appear to be the only cases, both legal and medical, involving minors as organ donors. Therefore it is important that they be analyzed in order to determine how they relate to twin and non-twin donors and what their effect will be on the doctor who is confronted with the legal dilemma of the minor donor.

²⁴ *Masen v. Harrison*, Massachusetts Supreme Judicial Court, No. 68651, June 12, 1957.

²⁵ *Id.* at 2.

²⁶ *Id.*

²⁷ *Id.* at 4.

The testimony of the psychiatrist does not appear to be as convincing as the court seemed to think it was. There are several reasons for this. It was stated that "a grave emotional impact would result". This in itself does not appear to be a very profound conclusion as it is one that almost anybody—especially the judge—could arrive at with a little thought.²⁸ Yet the whole opinion of the court is based on this one opinion which leaves the door open for almost all donors to donate since any child of normal intelligence would suffer grave and emotional impact if his mother, father, brother or sister died and a donation of one of his organs would have saved this relative's life. And since a child would generally be a good donor for such a relative (because of the genetic similarity) there would seem to be no limitations upon this doctrine.

In addition performing the kidney operation under this theory still does not *benefit* the child in the same way that other surgical procedures may. It only serves to *prevent* his suffering a predicted grave emotional impact, instead of *correcting* or *repairing* a defect. In a jurisdiction where the minor was not allowed to donate, this grave emotional impact might not result because the minor could legally do nothing to save his twin.

The court talks in somewhat confusing terms when it is considered that a seven-year-old child could become a donor under this psychiatric test. This view is softened somewhat by the court's finding that Leonard understands the operation and the possible risks and consequences thereof. In the *Masden* case the twins are nineteen-years-old. This is an age at which a youth can very easily understand the consequences and risks inherent in such an operation. But the Huskey and Foster twins were only fourteen-years-old. Yet the court decided that they were fully informed and consented to the operation with a thorough understanding of the consequences and attendant risks. This is incredible. It is almost beyond belief to think that a fourteen-year-old child could have the ability to understand such a problem, no matter how well the physician might have attempted to explain the risks to him. Thus, it appears that the *Masden* test, which theoretically would have allowed a minor to donate only where there was an informed consent by one capable of understanding the risks and consequences of the nephrectomy and where there was psychiatric testimony as to the prevention of emotional impact on the healthy twin, has degenerated into a test involving only psychiatric testimony which itself is nothing more than a common sense opinion by one who can conceive of the closeness of family ties. This test appears to be unsound. This viewpoint is reinforced by the fact that there have been no other reported cases where minors have actually served as the donor. Doctors themselves are reluctant to use minor donors because the risk of civil action by the

²⁸ Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U. L. REV. 891, 894 (1959).

donor upon reaching his majority and the attendant bad publicity which might hurt his professional status. A careful inspection of this "grave impact" test leads to one further conclusion. A child in his early teens is very susceptible to family pressures—even those indirectly asserted. Thus, in a situation where the child was the only possible donor the child would be forced by family pressure into a situation where "grave emotional impact" would result if he did not donate; but no such impact would result if it were legally impossible for the child to donate because of his age because there would be no reason for family pressure to be exerted.

These three cases leave several key issues unanswered. The Massachusetts court talks of informed consent on the part of the donating twin; but is this really necessary? Should a twin refuse to give his consent, is parental consent enough if a benefit can be shown to accrue to the donor twin? Is it enough if there is no more benefit than that demonstrated by the psychiatric testimony in *Masden*? Suppose the twins consent but the parents do not? These hypothetical questions point out legal difficulties which were not discussed in *Masden* or any other known case. Although these questions have not as yet arisen, with the ever increasing frequency of transplant operations and the desirability of performing them on youths they are certain to arise.

There are several reasons for the expanding opportunities for organ transplantation in youths. The first is sheer numbers. It is generally considered that within the next decade over one-half of the world's population will be under twenty-five. This means that a great deal of this percentage of this population will be under twenty-one. Second, young people are usually better able to withstand surgical procedures involved in organ transplantation and to fight off infections which set in as a result of the lowered body resistance caused by the ALG procedure for suppressing the rejection process.

In this area the physician is faced with a dilemma. Legally, he is prevented from using a minor as a donor. Medically, he realizes that the minor is better able to withstand the surgery than his older counterpart. A hypothetical situation illustrates the dilemma. A young man suffers from chronic uremia and will die without a transplant. Histocompatibility tests show two possible donors: the patient's nineteen-year-old sister and his forty-nine year old mother. The mother would like to donate but because of her age and commitment to other children in the family feels that she just cannot do it. The nineteen-year-old sister, an honor student at a large midwestern university, fully understands the risks involved and desires to donate one of her kidneys. But the doctor refuses to allow her to donate on the basis of the above mentioned *Masden* case. He feels that it is not worth the risk to his professional standing and medical career should he subsequently be sued in an action for battery. In

the light of the uncertainty of today's law the doctor is certainly justified in taking his position. After all, he has other patients who would suffer from a lack of his services if his license to practice is revoked. The problem is obvious, but what is the solution?

Legislation seems to be one solution. A law enabling eighteen year old persons to donate their organs should receive approval from both the medical and legal professions. Persons under eighteen would not be allowed to donate for any reason. At the age of eighteen a normal person is fully capable of understanding the risks inherent in a transplant procedure. He is also mature enough to make up his own mind without being pressured into it by family ties. Even the law recognizes this by the fact that in many states people make wills at the age of eighteen and in some states may even vote at eighteen.

By refusing to allow persons below the age of eighteen to donate, the occasion for pressure and uninformed consent is eliminated in those instances where it most often could exist. Also, by placing a definitive restrictive age on donation the medical profession can more clearly evaluate the possible range of donors and advise the patient.

The dangers in donating an organ are generally minimal. However, there are definite dangers and the minor should not be allowed to donate until he is fully able to comprehend the dangers or some benefit accrues to him as a result of the donation.

C. Prisoners as Donors

Prisoners represent a unique possibility for organ supply in tissue transplantation. In the past prisoners have often been used as guinea pigs in medical research. However, it was not until the transplantation "explosion" that the medical and legal professions took note of the tremendous moral and legal problems involved. There are estimates that as many as twenty thousand Federal prisoners are participating as volunteers in medical experiments.²⁹ Prison populations present an ideal group of subjects because of their controlled environment. "As the convicts have almost identical diets, sleeping hours and daily routine, they provide a most convenient set of subjects for controlled clinical trials."³⁰

Cancer studies have been undertaken at the Ohio State Penitentiary under the surveillance of the College of Medicine of the Ohio State University;³¹ leukemia experiments have been conducted at the Cook County Jail in Chicago³² and new drug experiments at the Oklahoma State Peni-

²⁹ FOX, CLINICAL PHARMACOLOGY AND THERAPEUTICS, 423, 425 (1960).

³⁰ PAPPWORTH, HUMAN GUINEA PIGS 67 (1967).

³¹ DONNELLY, GOLDSTEIN, AND SCHWARTZ, CRIMINAL LAW: PROBLEMS FOR DECISION IN THE PROMULGATION, INVOCATION AND ADMINISTRATION OF A LAW OF CRIMES, 79 (1962) [Hereinafter cited as CRIMINAL LAW].

³² Time Magazine, July 12, 1963, at 72.

tentiary.³³ The same considerations that have promoted experimentation on penal inmates in the past continue to operate and will promote transplantation on them in the future. The July 12, 1963, issue of *Time* magazine cited the following transplantation case:

An inmate of the Mississippi State Penitentiary at Parchman who was serving a life sentence for murder developed cancer of the lung. He was transferred to the University Medical Center at Jackson. His diseased lung was removed and he received the transplant of the lung of a patient who had recently died from a heart attack. The operation was not successful and the man died two weeks later.³⁴

In a series of procedures performed in Denver, Colorado, penal donors from three prisons were used in kidney transplants.³⁵ In this same series of operations the donors were also involved in a study of their motives for donating, the results of which will be discussed below.

As with the donors discussed previously, a freely given informed consent by the donor is often difficult to obtain and creates most of the legal problems in this area. At the present time the consent problem has not been dealt with as it directly pertains to organ donors. However, those medical personnel working with prisoners have generally attempted to get a valid, willing consent.

Generally those performing the experiment have indicated a desire to have a donor who is well informed as to the merits of the experiment as well as its risks and yet has not been coerced into his decision. There are two possibilities for coercion in this type of situation: (1) the prisoner could be deprived of certain privileges or punished for not volunteering or for refusing to continue to volunteer after he had once subjected himself to the whims of the medical researcher; (2) the medical researcher could offer rewards which would be excessive and therefore subject the prisoner to undue influence.

The first problem has been handled uniformly but the second has never really been solved. In 1948, Governor Green of Illinois set up a commission to report on the use of prison inmates as subjects for medical experiments. Among this committee's reports were the following recommendations on "ethical principles":

- (1) All the subjects should be volunteers. Volunteering exists when a person is able to say "yes" or "no" without fear of being punished or of being deprived of privileges due him in the ordinary course of events.
- (2) Before volunteering the prisoner must be adequately informed of any hazards that might exist in the experiment.

³³ *Id.*

³⁴ *Id.*

³⁵ ETHICS IN MEDICAL PROGRESS: WITH SPECIAL REFERENCE TO TRANSPLANTATION, 75 (G. Wolstenholme & M. O'Conner ed. 1966) [Hereinafter cited as MEDICAL ETHICS].

- (3) The choice of volunteers must be made on the basis of established criteria.³⁶

In addition to these so-called "ethical principles" the Green committee also considered financial and time-off rewards for participation in experiments.

The reduction of sentence in prison under the parole system is viewed as a reward for good conduct. Service as a subject in a medical experiment is considered to be a form of good conduct.

A reduction of sentence in prison, if excessive or drastic, can amount to undue influence. If the sole motive of the prisoner is to contribute to human welfare, any reduction in sentence would be a reward. If the sole motive of the prisoner is to obtain a reduction in sentence, an excessive reduction of sentence would exercise undue influence in obtaining the consent of prisoners to serve as subjects would be inconsistent with the principle of voluntary participation.³⁷

These opinions and recommendations sound nice but they do not answer the basic questions: should monetary rewards or time-off rewards be given? If so, how should the amount of money or time-off be computed?

In the cancer study at the Ohio State Penitentiary it was made explicit that there would be no rewards given and no money paid to the prison inmates for volunteering. An article appeared in the Ohio Penitentiary News entitled "Volunteers Needed for Seventh Phase of Cancer Research"³⁸ in which it was explained that six previous steps in a cancer research program had been conducted at the institution and that volunteers were needed for the seventh phase of the experiment which was being sponsored by the Sloan-Kettering Institute for Cancer Research of New York City. Doctor Charles A. Doan, Dean of the College of Medicine of the Ohio State University participated in the experiment. The article further stated:

Your warden [Alvis] approved and allowed the research to be conducted here only when he was well satisfied that this particular research was vital; would result in important information; and would not result in any particular harm to the men who would ultimately volunteer.³⁹

The article then continued to explain the procedures involved in the experiment, the purposes, and the duration of time for which a volunteer must sign up.

A prisoner's release form was included in the article and has been set

³⁶ Green Committee, *Ethics Governing the Service of Prisoners as Subjects in Medical Experiments*, 136 J.A.M.A. 457, 458 (1948).

³⁷ *Id.*

³⁸ Ohio Penitentiary News, LXVI, Jan. 3, 1959, at 1, col. 1, as quoted in CRIMINAL LAW, at 79.

³⁹ *Id.*, at 80.

out in a footnote.⁴⁰ This form contains several unique features. First, the experiment is carefully explained to the person signing the statement of consent. Second, there is no mention of any type of remuneration, i.e., either payment, time-off for good behavior or privileges. This form differs from an analogous form used at the Stateville Penitentiary which was used to describe the experiment.⁴¹

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Prisoner's Release Form

(Date)

Gentlemen:

I, _____, of the Ohio Penitentiary, # _____ and being of the age of 21 years or more, hereby volunteer myself freely and of my own will as a subject for experimentation in connection with a study of cancer, to be carried out under the joint supervision of the Division of Medical Research of the College of Medicine, The Ohio State University, and the Sloan-Kettering Institute of New York City.

This study, as it has been explained to me, is intended to determine whether or not presumed killed cancer cells can be successfully used to immunize against living cancer cells. I have been told that the cancer cells will be transplanted to my body by means of direct needle injection under my skin. I further understand that if the subsequent cancer transplant is successful that its existence will be observed for an indefinite period (whether I am still an inmate of the Ohio Penitentiary or not, or am transferred to one of its branches). Further, I will readily agree to submit to a surgical excision of the involved area at any time or to a biopsy of adjacent (nearby) areas of my body upon the request of the principal investigators, Doctors Charles A. Doan, Alice E. Moore, and Chester M. Southam, or their associates. It is expected that if the transplant survives that the entire growth will be removed. From time to time a sample of my blood will be drawn for analysis during this study.

I also hereby agree that I will not donate any of my blood to the American Red Cross for transfusion until a release for same is obtained.

(Signed)

Witness

(Name)

(Address)

Witness

(Name)

(Address)

The organizations involved in this study agree to pay for any and all medical care, special treatment, biopsies, etc., that may be necessary in connection with this study.

⁴¹ I . . . , No. . . . aged . . . , hereby declare that I have read and clearly understood the above notice, as testified by my signature hereon, and I hereby apply to the University of Chicago, which is at present engaged on malarial research at the orders of the Government, for participation in the investigations of the life-cycle of the malarial parasite. I hereby accept all risks connected with the experiment and on behalf of my heirs and my personal and legal representatives I hereby absolve from such liability the University of Chicago and all the technicians and assistants taking part in the above-mentioned investigations. I similarly absolve the Government of the State of Illinois, the Director of the Department of Public Security of the State of Illinois, the warden of the State Penitentiary at Joliet-Stateville and all employees of the above institutions and Departments, from all responsibility, as well as from all claims and proceedings or Equity pleas, for any injury or malady, fatal or otherwise, which may ensue from these experiments.

I hereby certify that this offer is made voluntarily and without compulsion. I have been instructed that if any offer is accepted I shall be entitled to remuneration amounting to . . . dollars, payable as provided in the above Notice.

This form appeared in PAPPWORTH, HUMAN GUINEA PIGS, 62 (1967).

In a letter from Charles A. Doan, M.D. to J. Goldstein, dated January 15, 1959, the procedure was explained as well as the fact that there was no coercion and no pressure of any kind.

. . . [A] copy of the release form . . . is signed in duplicate and with two guard witnesses. Dr. Southam from the Sloan-Kettering Institute for cancer research, Dr. Brooks, the prison physician and I meet with each new group and explain in detail the objectives of the research and the things that will be done in order to accomplish the necessary observations over a given period of time . . . the blood samples, the inoculations and the biopsies are explained in detail—any and all questions are answered and any individual who wishes to withdraw from the experiment is given ample opportunity and is urged to do so if he has any reservation at all.

Practically all of these men have close relatives who have been or are sufferers from cancer, and have individually expressed themselves as more than willing to try and advance our knowledge of cancer through participation in this program. Absolutely no coercion or pressure of any kind is used, and there are no special privileges granted to these men because they participate in this program. They continue to be ambulatory and do their regular prison jobs throughout the entire experiment.⁴²

In the Denver prison where the penal inmates volunteer their kidneys for transplantation no pay was involved and there was no reduction in sentence. As an indication that there was no coercion, only a little more than two percent (100 out of 4,000) of the prisoners volunteered.⁴³

In the case of the cancer experiment at the Ohio Penitentiary the intention of the doctors and the Sloan-Kettering Research Institute is admirable but somewhat unrealistic. By stating that no privileges were granted the Dean is attempting to prove that there was no element of coercion or pressure in the method of obtaining consent. A little reflection on this matter leads to a contrary conclusion. Most prison inmates will eventually be released from prison on parole or when their sentence has been served. Their complete record is considered whenever a hearing comes up as to whether parole should be granted or not. One of the prime considerations is good conduct. Even without stating that a prisoner would get time off for voluntary subjection to medical experiments this is one phase of good conduct and will be considered. Thus there is an element of coercion present. The prisoner generally knows how the parole system works and what factors are considered. But how does this affect the prisoner, and is it good or bad?

A prisoner who donates an organ for humanitarian reasons such as those suggested in Dean Doan's letter should definitely have this considered when he comes up for parole or is given time off for good behavior. In this case it probably makes little difference if he is given advance information as to how volunteering will effect his sentence. He would

⁴² CRIMINAL LAW at 80.

⁴³ MEDICAL ETHICS at 75.

volunteer anyway. But the "hardened criminal" is another problem. He may do anything to shorten his sentence. This prisoner uses the experiment as a means to an end which is not desirable from the general public's point of view.

The study conducted at the Harry S. Truman Laboratory, *supra*, also delved into the problem of why convicts volunteer for experiments. The results are somewhat surprising. In "Study No. 1—Why Prisoners Volunteer" the objective was "to determine why prisoners did or did not volunteer as subjects in a search for new antimalarial drugs and the extent to which they understood the element of risk involved."⁴⁴ Each inmate was told he would get paid but could expect no reduction in his sentence. Each physically fit volunteer was given an informed consent form to read and sign. During the course of the experiment the risk involved (which was almost non-existent) was continually explained to the volunteers. After the conclusion of the experiment two groups were questioned. Group number one was comprised of physically fit prisoners to whom the experiment had been explained but who had decided not to volunteer. Group number two was comprised of physically fit prisoners to whom the experiment had been explained, who had volunteered for the experiment and had thereafter received greater explanation of the experiment, its purposes and attendant risks. The inmates who participated in the project did not understand the disease or its risk any better than those who had not participated, even though they had received detailed information throughout the program. The volunteers also described the project in terms of "high risk" even though the physicians explained that the risk was minimal.

This study indicated that the prisoners did not first consider the risk and information provided before volunteering. The risk was not even considered. About half the participants gave "altruism" as the reason for volunteering; the other half gave money as their reason. Nearly all the non-volunteers believed it was an act of courage to volunteer.

The almost universal respect among nonvolunteers for those who did volunteer may offer some clue to the other group's reasons for volunteering. Although society at large regards prison life as having low status and few privileges, a system of privileges and status does operate within the prison itself. In a county jail [as this was], however, the opportunities to assert ones superiority are few, and those that do exist are open to a limited number of inmates. Projects like the malaria experiment provide many with a real chance to demonstrate their importance, not only to other inmates, but to the "square Johns", and it is possible that this consideration takes precedence over the weighing of risk and benefit implied by the informed-consent procedure.⁴⁵

⁴⁴ Martin, Arnold, Zimmerman, and Richart, *Human Subjects in Clinical Research*, NEW ENG. J. MEDICINE 1427 (1968).

⁴⁵ *Id.* at 1427-1428.

It is noteworthy that there is no talk of parole or its consideration by the prisoners. The reason is that all the prisoners contacted in this experiment were serving sentences of 1 year or less and thus it was not a major consideration.

This study and the previous comments lead up to the conclusion that the "informed consent" rule is simply not an effective tool in the naturally coercive atmosphere of a penal institution. Although it is true that transplantation itself has not as yet reached the point where prisoners are a major supply it is time to consider the problem. Transplantation has brought many other problems to a place of prominence and is likely to do so with penal donors.

The Denver experiment utilizing penal institution donors was subsequently discontinued when the transplantation committee at the University of Colorado decided "that the use of penal volunteers, however handled in a local situation, would inevitably lead to abuse if accepted as a reasonable precedent and applied broadly."⁴⁶ It seems more than possible that the physicians involved were afraid that such conceivable abuse might lead to repercussions affecting the whole field of transplants—a phenomenon which the physicians definitely do not want.

The problems in this area are present and undoubtedly will continue. As long as there are prisons with their ideal experimental and control possibilities there will be physicians desirous of conducting experiments—especially transplant procedures—on the inmates. Clearly in some cases there is nothing wrong with this, in some instances. Lawyers should cooperate with the medical personnel and institutional personnel to arrive at a solution which prevents coercion and undue influence, yet allows the willing donor to give his organs. There is no reason why prisoners could not be paid for their time spent in experiments just as they are paid for other work at the penitentiary. That is, they would receive the same rate of pay. Thus there would be no monetary reasons coercing an inmate to choose experimentation over any other type of work.

For that group of prisoners who are considered "hardened" and should be kept in jail without time off for good conduct, the prison officials could simply not allow these men to volunteer. Then everybody who did volunteer would have their volunteering considered to be just one of the many factors to be considered in granting parole or time off for good behavior. If a prisoner's intentions are good there is nothing wrong with allowing him to "prove" to the parole board that he is a worthwhile individual. Volunteering for medical experiments in the form of donating kidneys is just one means of proving this.

⁴⁶ MEDICAL ETHICS at 76-77.

D. Necessary Donors

The fourth category of donor is that person who must give up an organ in order to live. One example is the hydrocephalic child who must give up one of his kidneys as a result of the surgical procedure involved.⁴⁷ A second example is where a kidney is removed because of a disease in the lower ureter or in the performance of a ureteric subarachnoid anastomosis.⁴⁸ In these situations the ordinary problems of kidney donation are absent. The healthy kidney is simply a by-product of the life saving procedure. Once it has been decided that a kidney must be removed the surgeon looks around for a potential recipient. When a compatible recipient has been found and the consent forms have been signed the removal and transplantation into the recipient are performed.

E. Cadaveric Donors

The cadaveric donor presents many unique problems—several of which may have been solved by the recent promulgation of the Uniform Anatomical Gift Act. A brief history into the common law of bodies is necessary to fully comprehend several of the present day problems. Such a background is the subject of a 1966 annotation:

Under the early English common law, no rights in property in a dead body were recognized. From this it followed, quite logically, that a dead body could not be the subject of a testamentary bequest, and a testator's directions for the disposal of his remains were merely a request without probative effect.

Although the English rule that no rights of property existed in a dead body was originally adopted in this country, courts recognized quite early that although a corpse was not property in a commercial sense, it possessed many of the attributes and was frequently described as "quasi-property". Having recognized certain property rights in dead bodies, many courts have announced the rule that a person has a right to dispose of his own body by will. However, courts, while paying lip service to the doctrine of testamentary disposal, have in certain instances permitted the wishes of the decedent's spouse or next of kin to prevail over those of the testator. In other instances courts have accepted and acted upon evidence that indicated that the decedent's wishes concerning the disposition of his body had changed since the execution of his will. Courts have also ruled that because of lapse of time, or some prior disposition of the decedent's remains, the performance of the testator's wishes had become impossible of performance.

In the absence of specific statutory authority, a person has, at best, a very qualified assurance that the testamentary disposition that he makes of his own body will be fulfilled. This appears particularly true if his will provides for disposition by some means other than interment. And

⁴⁷ MOORE at 61.

⁴⁸ CALNE, RENAL TRANSPLANTATION, 149 (1967).

the chances against fulfillment become vastly greater if he desires to donate his body, or parts thereof, for scientific or medical purposes.⁴⁹

In the past few years legislatures, who began to realize the lag inherent in their field, have begun to do something about it. What exactly is the problem with which they are faced?

Individuals generally die from a combination of causes. But it is certain that at the instant of death, certain organs are still functioning and capable of doing so for some time in the future. Therefore, it is possible for these organs to be a source for use in tissue transplantation. The problem of cause is consent—whose? In the past the consent of the deceased would not have been enough. That is, even though the deceased gave consent, the next of kin might decide that he or she did want any part of the body of the deceased removed; and thus there were no organs to be transplanted. The reasons for this are fairly obvious. If the state was one in which the decedent's testamentary disposition was not effective because of the common law rule then there was simply no way to get around the refusal of the next of kin. But what about those states giving respect to the wishes of the dead? Here two factors must be considered. Although the doctor or potential recipient can go to court and get the organ(s), in so delicate an area as transplantation the medical profession simply does not want to create a public spectacle. It looks bad and will greatly hinder the success in obtaining future donors. Secondly, if any time goes by at all, as explained previously, the organ will have lost its viability and could not possibly be successfully transplanted.

Some states realized this problem and began to enact statutory authority for the donation of bodies or organs to specific individuals, medical schools, hospitals, and doctors. Thirty-nine states and the District of Columbia have general donation statutes while four more states authorize the gift of eyes only.⁵⁰ Each of these statutes is different as to permissible donors, means of donation, revocation, number of witnesses and age of the donor. Ohio has a fairly comprehensive statute.⁵¹ The

⁴⁹ Annot., 7 A.L.R.3d 747, 748-49 (1968). See also WASMUTH, *LAW FOR THE PHYSICIAN*, 453 (1966), Comment, *The Law of Dead Bodies: Impeding Medical Progress*, 19 OHIO ST. L.J. 455 (1958); 45 CHI-KENT L. REV. 78, 80 (1968).

⁵⁰ UNIFORM ANATOMICAL GIFT ACT at 5. The states are as follows: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and the District of Columbia. Georgia, Maine, New Jersey and South Carolina authorize gifts of eyes only.

⁵¹ OHIO REV. CODE ANN. ch. 2108.01 (Page, 1953):

§ 2108.01 Instrument of gift of body; rights of next of kin and donee.

A person who is twenty-one years of age or older and of sound mind may make a gift of all or any part of his body effective upon his death, by a written instrument signed by him or by some person in his presence and at his express direction and subscribed by two witnesses in the presence of the donor and each other who shall have no

provisions are somewhat progressive in comparison to the acts of other states and agree to a large extent with the provisions of the Uniform Anatomical Gift Act which will be discussed below. It also has many of the same defects.

Problems have developed because of the fact that people in this country move from state to state. Since the requirements for making donations are different in each state the National Conference of Commissioners on Uniform State Laws at its July, 1968, meeting, drafted the Uniform Anatomical Gift Act and approved and recommended it for enactment in all the states.

The Uniform Anatomical Gift Act is limited to ante-mortem gifts. It does not cover the present day problem of inter-vivos gifts, such as kidneys from a living donor to his sister. A summary of the act follows:

(1) The gift may be made by a person of eighteen years or older during his lifetime to take effect upon his death. If the decedent has not made such a gift it may be made by his relatives, next of kin or guardian according to a stated order of priority. But the donee may not accept

affiliation with the donee or the donee institution. Such a gift made in a written instrument is effective without delivery or acceptance and may be revoked in the same manner as executed. If the entire body has been donated; next of kin may arrange funeral services or other last rites before the body is claimed by the donee.

The rights of a donee or his agent under such a gift are superior to those of any person claiming as spouse, relative, guardian, or in any other relationship, as such rights may be limited by the instrument of donation.

A gift made under this section, in addition to the authorizations contained in the instrument of gift, authorizes the donee or his agent to perform only the surgical procedure necessary to carry out the gift. A donee may employ or authorize any licensed physician or surgeon to carry out necessary surgical procedures. When the gift is of only a part or parts of the body, immediately following the removal of the part or parts named, custody of the body, shall be transferred to the next of kin.

§ 2108.02 Authorized donees.

The following persons may be named as donee in a gift made under section 2103.01 of the Revised Code for the purposes indicated:

(A) A licensed physician or surgeon, or a hospital, for medical education, research, the advancement of medical science, aid in therapy, or for transplantation to replace diseased or deteriorated parts of other persons;

(B) A medical school, college, or university engaged in medical education and research, for its educational research or scientific purposes;

(C) A non-profit blood bank, artery bank, eye bank, or other storage facility for human parts to be used for therapy or transplantation for other persons, or for medical education and research;

(D) A named individual for transplantation or therapy needed by him;

(E) Any licensed physician or surgeon claiming the body, not naming him, for any of the above purposes

If the donor so provides in the instrument of donation, in the event transplantation to a named donee is not feasible, removal for transplantation may be made for any person by a licensed physician or surgeon, who is the alternate donee for such purpose.

§ 2108.03 Liability for damages.

A person who, in good faith and acting in reliance upon an authorization made under Chapter 2108. of the Revised Code and without notice of revocation thereof, takes possession of, performs surgical operations upon, or removes tissue, substances, or parts from a human body, or who refuses such a gift, or any person who unknowingly fails to carry out the wishes of the donor according to Chapter 2108. of the Revised Code, is not liable for damages in a civil action brought against him for such act.

the gift if he knows that the deceased or someone of higher priority than the one giving permission would have opposed such a gift.

(2) Any hospital, surgeon, physician, teaching institution, organ storage bank or specified individual may be the donee as long as the purpose of the gift is for medical or dental education, research, advancement of medical or dental science, therapy or transplantation.

(3) An anatomical gift may be executed by a will which becomes effective upon the death of the donor without waiting for probate and which is valid and effective if acted upon in good faith even though subsequently declared invalid for testamentary purposes. Any document may be used to make the gift as long as it is signed by the donor in the presence of two witnesses who sign the document in his presence. The act specifically allows a credit card type of card to be used to make a gift as long as it is signed as above. If the gift is not made to a specified donee the attending physician may accept the gift as the donee but he may not participate in the procedures for removing or transplanting a part unless he is so indicated in the document creating the gift.

(4) Delivery of the document creating the gift is not necessary but the Act provides that delivery of such document may be made to expedite the appropriate procedures after death.

(5) The Act provides that if delivery of a document has been made to a donee the donor may amend or revoke such gift by a statement—either oral or in writing—communicated to the donee or a signed card or document found on his person or in his effects. Any undelivered document of gift may be revoked in the above manner or by destruction, cancellation or mutilation of the document and any copies thereof. Gifts made by will may be amended or revoked in the manner provided for under state law for the amendment or revocation of wills or in the same manner as for delivered documents.

(6) The donee may accept or reject the gift. If he accepts he may use those parts given to him and then custody vests in that person(s) under obligation to dispose of the body. The time of death is determined by the attending physician and anyone acting in good faith under the terms of the act is neither liable in a civil act for damages nor is he subject to criminal prosecution.

There are several aspects of transplantation with which the act does not deal.⁵² The Act has made no attempt to define the time of death. A comment to the Act specifically refers to this matter:

no attempt is made to define the uncertain point in time when life terminates. This point is not subject to clear cut definition and medical authorities are currently working toward a consensus on the matter. Modern methods of cardiac pacing, artificial respiration, artificial blood cir-

⁵² Stason, *The Uniform Anatomical Gift Act*, 23 BUS LAW. 919, 927-929 (1968).

culation and cardiac stimulation can continue certain bodily systems and metabolism far beyond spontaneous limits. The real question is when have irreversible changes taken place that preclude return to normal brain activity and self sustaining bodily functions. No reasonable statutory definition is possible. The answer depends upon many variables, differing from case to case. Reliance must be placed upon the judgment of the physician in attendance. The Uniform Act so provides.⁵³

This is a serious omission and will be dealt with later. The Act also omits reference to payment for the gifts. At first glance it seems that payment for gifts offends the dignity of death which goes with such a gift. Yet if kept within control there is no reason why payment should not be received as it is often given for blood. But this is not to say that problems may not develop. A brief inquiry leads to the situation where the dying person's next of kin is approached about selling organs and is offered a high price. An unscrupulous next of kin may feel that the dying person does not want his organs donated but feels there is no danger of it happening and so says nothing. Thus there is a potential problem which should have been dealt with. It will certainly develop as transplants of all kinds become more prevalent. The answer is not simple and the legislation will be difficult to draft—but it should be attempted.

No provision is made for establishing who is to receive the donated organs in a situation where a specific donee is not specified. That is, who gets the organ when a hospital or physician is the donee? Can the organ then be implanted into anyone? The problem has thus been left to the doctor to decide. At the present time, when transplantation is still in its youth, this is permissible because the doctor generally does not have a great number of recipients to choose among. That is, a given donor is generally histologically compatible with a small number of possible donees. But as transplantation skills increase, it may become a problem and doctors will definitely need standards that enable them to choose the proper donor. This could have been provided for and will be discussed later.

The definition of death problem mentioned above has come to the forefront with the successful performance of the heart transplant, although it exists every time any organ is removed from a cadaver and transplanted into a waiting recipient. The problem is simple but the solution is complex.

Briefly stated the problem is all a matter of time. As previously stated organs lose their viability a short time after death. Thus the successful performance of any transplant requires that the organ be removed as soon as possible after death in order that the transplant succeed. Until recently the layman, lawyer and physician determined death by the same criterion. This was the so-called "clinical-death" which resulted when

⁵³ UNIFORM ANATOMICAL GIFT ACT at 19-20.

there was a cessation of the heart beat and breathing had stopped (often shown by holding a mirror close to the deceased's mouth to see if it clouded up by breath).⁵⁴ But these criterion are no longer definitive of death in the large university or leading hospital where miracle machines and techniques are used to maintain body functions. The heart-lung machine is capable of pumping blood through the circulatory system while oxygenating it at the same time. To aid a weak erratic heart which has all the tissues intact, the electronic pacemaker has been developed to stimulate the heart by means of electrical impulses so that it beats at a predetermined rate. Respirators are a common means of aiding a patient to breathe when he cannot otherwise breathe by himself. Thus the medical profession has succeeded in maintaining heart beat and breathing and thus destroying the indicators of clinical death. Originally these machines were developed to provide temporary relief from certain problems but have instead become a means of prolonging life when in fact no meaningful life is possible.

Generally medical personnel have come to agree that meaningful life is no longer possible when there is no possibility that the brain will continue to function. That is, if the brain continues to function with the respirator and heart-lung machine hooked up there is life, but otherwise there is none. The concept of death is important outside the scope of transplantation.

Many people are now maintained in a sort of twilight state by the use of machines which do the work of their lungs or their heart while they are completely unconscious. Many of these people will never resume an independent existence away from the machines, but they can't stay on the machine for ever and ever. There just aren't the machines and there isn't a place to park these people. One has to decide therefore when to switch off the machines, and this question arises quite independently of considerations about transplants.⁵⁵

Thus there are a great many considerations to be kept in mind in transplant and nontransplant situations in determining death.

The problem of informed consent is certainly important in this area. A person may not want to donate organs during his lifetime but may be more than happy to do so at his death. But when he consents he may want some assurance that he will really be dead. What can the doctor tell him? What can the doctor do to assure the next of kin that the proposed donor is really dead? The problem is that miracle recoveries do exist and are in the back of every donor's mind (or his next of kin's mind).

In the summer of 1967 U.S. Infantryman, Specialist 4th Class Jacky

⁵⁴ N. Y. Times, May 19, 1968, at 78.

⁵⁵ MEDICAL ETHICS at 71.

C. Bayne "died" from wounds suffered in Viet Nam. For 45 minutes doctors had applied external cardiac massage and artificial respiration until his electrocardiograph showed no heart activity. A few hours later, as the embalmer was preparing to inject embalming fluid a flicker of pulse was discovered. He was rushed back to the hospital where he was revived. He is now back in the United States, receiving rehabilitation treatment.⁵⁶ The Soviet physicist Lev Davidovich Landan was gravely injured in an auto accident in March, 1962. Four days after the accident his heart stopped beating and his arterial blood pressure dropped to zero. Clinically he was dead. The doctors revived the heart with injections of adrenaline, strophanthin and blood injections. Landan's heart stopped three more times during the next week and each time the doctors brought him back. After lying in a coma for sixty days he regained consciousness and his memory and power of speech. By December, 1962, he had recovered enough to receive the Nobel Prize in physics.⁵⁷ With these sensational recoveries brought to the public's attention through sensational newspaper reports, several problems develop. First, a donor (or his next of kin) may develop the idea that these extraordinary life saving techniques will not be used to keep him alive if the organs of his body are to be donated. Second, in a situation where life has already ceased to exist the doctor, in order to avoid civil liability may feel compelled to use extraordinary life saving techniques, at a great cost to everyone, when the need for such techniques has long since passed. The solution to this problem is difficult and yet the mechanics are simple.

A statutory definition of death may be impossible. But there are other ways to meet the problem. Standards for determining death are possible and should be enacted by the legislatures to implement the criteria set up by the medical profession. A few suggested criteria are set out below.

- A. Death is the *final and irreversible* cessation of *perceptible* heartbeat and respiration. Conversely, as long as *any* heartbeat or respiration can be perceived, either with or without mechanical or electrical aids, and regardless of how the heartbeat and respiration were maintained, death has not occurred. [Emphasis in the original.] The measurement of brain activity is presently possible in only those isolated cases where death occurs in the operating room or on the examination table. For this reason, the use of these phenomena as a guidepost has been purposely excluded from the definition.⁵⁸
- B. Death is an irreversible cessation of *all* of the following:
 - (1) Total cerebral function, (2) spontaneous function of the respiratory system, (3) spontaneous function of the circulatory system.Special circumstances may, however, justify the pronouncement of

⁵⁶ N. Y. Times, April 21, 1968, at 119.

⁵⁷ *Id.*

⁵⁸ 3 HOUTS, & HAUT, COURT ROOM MEDICINE, § 1.03(4) (1968).

death when consultations consistent with established professional standards have been obtained and when valid consent to withhold or stop resuscitative measures have been given by the appropriate relatives or legal guardian.⁵⁹

- C. Human life continues for as long as its vital functions, distinguished from the simple life of the organs, manifest themselves without the help of artificial process.⁶⁰
- D. The Neurology Department of the Southwestern Medical School at Dallas, The University of Texas submitted the following criteria for complete cerebral death in the presence of heart beat and relatively normal blood pressure:
 - (1) There would be no electrical activity of the brain, as shown by completely flat electroencephalograph lines, even with high amplification. There would be no EEG response to pinch or noise.
 - (2) There would be no spontaneous respiration. (In such cases the respiration would be solely supported artificially.)
 - (3) There would be no reflexes of the pupils or tendon reflexes and no pulse change from eyeball pressure.
 - (4) There would be no eye response to stimulation with 200 milliliters of ice water in each ear—tested separately.
 - (5) That this state (Nos. 1, 2, 3 and 4) must persist unchanged for at least two hours.
 - (6) All such patients must also have no evidence in blood samples of toxic levels of central nervous system depressants such as might be used in a suicide attempt.

On fulfillment of these standards, the neurologist, with the concurrence of one or more colleagues, would certify that the patient is neurologically nonviable or has reached the point of cerebral death. The neurologists would in no other way be involved in determining the suitability of the donor, or in problems of care of either donor or recipient.

Finally, it will be the policy of Southwestern that no transplant will be done if there is any suspicion the donor was involved in a homicide.⁶¹

- E. On August 9, in Sydney, Australia, the World Medical Association adopted a statement on death called the Declaration of Sydney. The statement does not attempt to define death. It contains the following statements:

The determination of the time of death is in most countries the legal responsibility of the physician and should remain so. Two modern practices in medicine, however, have made it necessary to study the question of the time of death further: (1) the ability to maintain by artificial means the circulation of oxygenated blood through tissues of the body which may have

⁵⁹ Halley, and Harvey, 204 J.A.M.A. 423 (1968).

⁶⁰ Pope Pius XII, Quoted in N. Y. Times, May 19, 1968, at 78.

⁶¹ Unpublished Report, *Spectrum, A Report from the Dean*, Southwestern Medical School, Univ. of Texas, July 19, 1968.

been irreversibly injured; and (2) the use of cadaver organs such as hearts or kidneys for transplantation.

This determination will be based on clinical judgment supplemented if necessary by a number of diagnostic aids, of which the electroencephalograph is currently the most helpful. However, no single technological criterion is entirely satisfactory in the present state of medicine nor can anyone technological procedure be substituted for the overall judgment of the physician. If transplantation of an organ is involved, the decision that death exists should be made by two or more physicians and the physicians determining the moment of death should in no way be immediately concerned with the performance of the transplantation.

Determination of the point of death of the person makes it ethically permissible to cease attempts at resuscitation and, in countries where the law permits, to remove organs from cadavers. . . .⁶²

Inherent in these six definitions of death is the concept of complete cerebral death. In the first definition by Marshal Houts, which is the closest to the clinical death definition, it is recognized that the environment at the time of death is related to the problem. A man who dies at home in his sleep and is not discovered for several days is not important as a donor. His organs have lost their viability. The person who dies in a hospital is quite a different problem. Within minutes respirators and other machines may be hooked up in order to preserve his organs for transplantation. The problem is: How soon can death be recognized? At what point can we safely say that the man has ceased to exist as a human being and that his organs may be removed for transplantation? There is no doubt that the physicians in charge are competent to determine when a person is dead. The real problem is whether he may not "jump the gun" in declaring somebody dead so that his organs will be more suitable for implantation into a second individual. The criteria have been developed to prevent this from happening. But it does not seem possible to legislate standards such as these for the reason that they cannot be enforced. Paul J. Matte, after discussing organ transplants and human experimentation went on to say that:

. . . organ transplants . . . have introduced into a medical ethic . . . the need to define in ethical and theological terms that point at which an individual can be considered truly dead, or at a minimum to have lost his status as a human being. There is immediate need in these areas of medical practice for the drawing of legal lines beyond which decisions in terms of individual morality becomes permissible and relevant. . . . [A]nswers to these problems require much more than attention to a minimal morality of duty . . .

. . . [F]rom lawyers and physicians laboring at what has been called

⁶² *WMA Code Defines Death*, AMA News, August 26, 1968 at 3.

the interface of medicine and law . . . are most likely to come pragmatic solutions to these problems . . . [L]aw has incurred thereby an obligation which has at last come due, and a day has come when the law, as guardian of such minimal public morality as may be, must devote more of its time and talents to search for answers to questions where . . . issues are equivocal and precedents are silent. I do not believe the law will lack competence in these matters. However, I do fear that without organized pressure from the discipline of forensic science for a judicial, a contemplative, an investigative, or even a committee approach to these problems, the law of medical practice will again be plagued by ad hoc precedents and emergency legislation hastily contrived in response to public pressure and emotional reaction to particular medical calamity.⁶³

Dr. Matte's point seems clear. If something is not done about this moral matter by a concerned group of physicians and lawyers harmful results may occur. One can imagine the parade of horrors that might result if an important dignitary were to die because the plug was pulled too soon. A rash of unnecessary legislation would result that would successfully prevent any future transplantation. The lawyer as "the guardian of public morality" is faced with a dilemma. On the one hand he must be sure that the potential donor is protected from a premature death and also that the physician is not accused of murder. On the other hand, transplantation has been shown to be successful and he must not place any unduly severe restrictions on it which would prevent a recipient from enjoying years of productive life. This writer has no doubts that legislation will be forthcoming, but it must serve these ends. The physicians would do well to cooperate in its promulgation.

Legislation should not invade the medical province by imposing standards of death similar to those indicated above, but it can successfully encourage the adoption of standards by hospitals, etc. The solution involves the legislative adoption of a system of committees at each institution and a requirement that each committee set up its own standards which would be available to anybody and amendable at the insistence of the hospital staff. Adherence to these standards would absolve the medical profession from civil liability except for negligence.

Several systems have been suggested. The Stanford Medical Center has three committees of three members. One committee interviews the donor and must agree unanimously that he is suitable before he sees the surgeon. A second committee interviews the potential recipient and must unanimously agree that he is a suitable recipient and that the chances of success are good. Death is determined by a third committee whose members are obligated to do everything for him before he is declared dead and his organs are removed and distributed to waiting recipients. This death-determining-team is not related in any way with the actual trans-

⁶³ Matte, *Law, Morals and Medicine: A Method of Approach to Current Problems*, 13 J. FOR. SCI. 318, 331-32 (1968).

plant itself.⁶⁴ This watchdog procedure of separation of treatment and transplantation has generally been accepted by the medical profession.

There is little question but that it is unethical for a physician to treat both the donor and [the] recipient. Only after the donor's physician has given up hope and diagnosed the state of brain death can the transplant team ethically act or otherwise intrude itself upon the scene.⁶⁵

A second system involves a legislative enactment of a board of physicians at each hospital who function to determine brain death. This could also be a committee of three composed of an anesthesiologist, a neurologist and a specialist in internal medicine. If one of these were not available an outside physician from the particular specialty could be chosen by members of the hospital staff. In non-emergency situations this committee would meet to determine by unanimous approval if a patient had suffered cerebral death. If so, the treating physician would then be free to discontinue treatment. Then the transplant surgeon, with the permission of the treating physician would be free to remove whatever organs the patient or his next of kin had agreed to. The legislation should provide that the board's determination of cerebral death would be conclusive on that subject in any civil litigation in the event that the treating physician discontinued treatment and was subsequently sued in a wrongful death action. This proposed system also concludes that if the physician refused to discontinue treatment after a finding of cerebral death, a person liable for the payment of medical fees would be able to resist payment of fees for subsequent medical treatment.

Doctors generally appear to be against the use of committees in deciding death. The reasoning is based on the fact that large committees are generally not able to decide matters quickly. This matter of committees will be carefully considered in the section on recipients. However, it is probably the case that most physicians would not be opposed to small three man committees which could easily be convened and decide the matter on the basis of established criteria.

In the end the decision rests on the physician. Through years of training and experience he alone is qualified to determine when death has occurred. Even if standards have been set up, he alone can interpret and apply the facts to these criteria. The courts and legislatures should do no more than force the physicians to adopt standards and to be consistent. Such legislation would seem to be just what the doctors would want. By promulgating and adhering to a set of rules determining death the physicians associated with the transplant would have no civil liability to worry

⁶⁴ The National Catholic Reporter, June 26, 1968, at 6.

⁶⁵ Wasmuth, *The Concept of Death*, 30 OHIO ST. L.J. 32, 56 (1969).

⁶⁶ *Id.*

about. This in itself would be an advantage that the present system—if there is one—does not offer.

F. Animal Donors

The sixth possible source of organs is the animal donor. This possibility presents two major problems. First, the genetic difference between man and animals is very great. Therefore the immune reaction is very great and rejection of the tissue graft is extraordinary. Second, this type of procedure is very offensive to the dignity of man and thus has not been attempted as often as it perhaps should be. There have been no legal cases on this, but there have been several attempts at transplantation.

On November 3, 1963, in New Orleans, Dr. Reemtsma and his colleagues, working under the direction of Dr. Oscar Creech of the Tulane Medical School transplanted the kidneys from an 85 pound chimpanzee into a 37 year old man. The patient had been suffering from chronic glomerulonephritis and no cadaver was made available. The patient died eight weeks after the transplant. During that time the chimpanzee kidneys worked quite well and received a good supply of blood. The patient died as a result of the rejection mechanism.⁶⁷

This experiment was really quite amazing and opened the door for future experiments. In 1964 Mississippi's Dr. James E. Hardy performed the first transplant of a heart into a human patient using a chimpanzee as the donor.⁶⁸ Dr. Charles Hufuagel of the Georgetown University Medical School plans to expose the human-sized hearts of unborn calves to radiation (to eliminate the immune reaction) for ultimate transplanting in humans.⁶⁹

The advantage of using animal donors is enormous once the rejection problem is solved. There is no donor consent to obtain, there is a good supply of donors available at all times, the definition of death never enters the picture and the cost will be relatively cheap. Heterotransplants of this sort are sure to play a part in the future of transplantation and may well be one of the ultimate answers to today's problems.

G. Artificial Organs

The most recent source of organs for transplantation is the artificial organ. Many of the same medical problems develop in this area as with human organs. That is, rejection of the artificial organ occurs and blood clotting occurs. But this is getting ahead of the story.

The initial problem with artificial organs is developing one that can do the job. The artificial kidney is just such an organ. Although not

⁶⁷ MOORE at 139, 40.

⁶⁸ Time Magazine, Sept. 20, 1968, (Transplants).

⁶⁹ N. Y. Times (magazine) Apr. 21, 1968, at 118.

thought of as an organ replacement it really is. That is, it performs the same functions as a functioning kidney; it just happens to be a little bigger and is outside of the body. The same is true for the artificial heart that Dr. Michael E. DeBakey inserted in a woman patient on August 8, 1966, at the Methodist Hospital, Houston, Texas. In this operation the plastic artificial heart sustained a woman through a 31½-hour valve-replacement operation and enabled her to survive post operative heart failure on the sixth day. The artificial heart was removed on the 10th day after the heart had healed.⁷⁰ In the past several years the newspapers have periodically reported on the development of artificial arms controlled by currents from the wearer's muscles. The wearer simply thinks of moving his arm and up it goes.⁷¹

The problem with all these organs is the size, weight and power supply. However, there is really no doubt that these problems will be solved. One need only recall the recent Moon Flight of the Apollo in which a miniature camera with a tremendous power supply was used to televise pictures of the earth and the astronauts back to earth. In this day and age engineering problems can be solved if enough man-hours and money are donated to the problem.

Artificial organs will solve a great deal of problems in the same way the animal-donated kidneys may. There will be no problem of donor consent and no problem of definition of death. But other problems will develop. One is bound to be the prohibitive cost of such an organ. Silicon and other new materials have been developed which, because of the consistency of their surface, do not promote as severe a rejection reaction as do other metals and animal tissues. These metals and procedures used to produce them are bound to be expensive. The production of the miniature organs will result in a high price being charged for them. Thus only the affluent will be able to survive unless the government subsidizes the manufacturer of these organ replacements or pays the purchase price for those who are unable to afford them.

Assuming the cost problems are met and artificial organs can be easily obtained the lawyer and physician face a greater moral problem: Should anybody be allowed to receive such an organ regardless of the physical state of the rest of their body. To put it another way, should an eighty year old man suffering from terminal cancer be allowed to have a transplant? As long as there are enough organs to supply the needs of the population the answer would seem to be yes. In those situations where there are not enough organs to supply everyone's needs, a moral question of social worth may be involved. This matter is discussed below.

⁷⁰ BRITANNICA, BOOK OF THE YEAR 1967, at 528.

⁷¹ TAYLOR, THE BIOLOGICAL TIME BOMB, 84 (1968).

IV. RECIPIENTS

The recipient of a transplant organ presents the doctor with many problems which he may not be able to handle without outside help. The patients who suffer from acute renal failure or from heart disease have much the same problem and therefore only the kidney patient will be discussed. The patient enters the hospital without knowing what his chances for recovery are or what he will have to undergo. Initially, he is placed on a strict bland diet and undergoes peritoneal dialysis or hemodialysis on the artificial kidney. The doctors use this method for one of two reasons. First, the dialysis may relieve the kidneys of their function so that they may rest and repair themselves. Second, it may be the only way to keep the patient alive.

The transplant situation develops only in this second instance. The procedure, at the present time, is fairly simple from there on. The patient is apprised of the situation and that without a transplant he will soon die. As a result of the diagnosis, the patient agrees to a transplant, which is explained to him in great detail, and he signs the appropriate consent form.⁷² The surgical aspects of the procedure are explained to

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THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE
CONSENT FOR RENAL TRANSPLANTATION

I, _____, agree to accept a kidney transplant from either a living or cadaveric donor as determined by the physicians at O.S.U. Hospital. In addition, I realize that a successful kidney transplant requires the taking of drugs to control rejection that are still considered experimental. I agree to participate in the antilymphocyte serum program with the understanding that this material is being used as an aid in controlling rejection, and the possibility of the occurrence of fever, local pain, and allergic side effects have been explained to me.

Witness _____ Patient _____
Witness _____

The above form is that used by The Ohio State University Hospital.

REQUEST FOR KIDNEY TRANSPLANT OPERATION
IN RELEASE OF ALL CLAIMS

Whereas _____ born on _____ and residing on _____ has a serious kidney ailment and is in danger of losing _____ life unless an operation is performed on _____: and whereas certain doctors connected with the _____ Hospital are willing to perform this operation upon the said _____ in the hope of saving the life of the said _____ and whereas the doctors who propose to perform said operations and the _____ Hospital and its staff of doctors and medical associates wish to be absolved from any and all liability, damages, law suits and causes of action as a result of the operation, now therefore in consideration of the operation to be performed and any further operations which may in the opinion of those doctors be necessary therewith, we, _____ and _____, the intended recipient of the operation and the intended donor fully realizing that the operation may be unsuccessful and may result in either losing their life or in future physical incapacity, illness or illnesses directly or indirectly caused by said operation, we nevertheless both jointly and severally on behalf of ourselves, our heirs, administrators, executors, and assigns do hereby request that said operation be performed upon _____ and hereby RELEASE AND FOREVER DISCHARGE the _____ Hospital, its director, and all persons on its medical or surgical staff who are in any way directly or indirectly connected with said operations or any

the patient who is told that tissue transplantation is still considered experimental, that the experience may be painful and that the success can not be guaranteed.

The next problem involves the finding of a donor. The general practice is for the potential recipient to contact the members of his family to secure a donor. The relatives come in and undergo a tissue typing test to ascertain whether or not there is suitable histocompatibility. When a match is found the dangers and risks are explained to the donor. If there is no suitable donor, then the search turns to the cadaveric donor. As the Ohio State University consent form indicates, the physicians have the final say as to whether a cadaveric donor's or live donor's kidney is used. Generally, the patient takes whatever he can get and is happy for it. Assuming there is a donor, the operation proceeds and hopefully the recipient recovers to lead a normal and productive life.

Inherent in this scheme are few legal problems (other than consent). As the surgeon's skills in transplantation grow and the rejection mechanism is successfully combated a great many problems will be created. It has been estimated that 50,000 heart attack victims a year in the United States alone could benefit from new hearts.⁷³ The prefatory note to the Uniform Anatomical Gift Act indicates that between 6,000 and 10,000 lives could be saved each year by renal transplants.

As the public and medical spheres develop confidence in transplantation procedures, more and more people will turn to them as the last resort.

other future operations resulting from them, for our post-operative care while in the _____ Hospital, from all damages or causes of action, either at law or in equity, which we may have or acquire or which may accrue to us, our heirs, administrators, executors or assigns as a result of these operations or medical care arising therefrom. We intend this to be a complete RELEASE AND DISCHARGE of all persons as well as any corporate entity having anything to do with the operations and we intend hereby to RELEASE AND FOREVER DISCHARGE said persons from all liability whatsoever. It is clearly understood by all parties to this instrument that no representations have been made to any of us regarding the success of the operations, and we fully understand that said operations are somewhat in the nature of an experiment and are being performed in the hope of saving the life of the said _____. We have read all the statements contained herein and we fully realize that *we are signing a complete release and bar to any further claims which we may have resulting from these operations.*

DONOR

RECIPIENT*

PARENT

PARENT

WITNESS

DATE

*Should recipient be a minor, the signature of both parents must be obtained.

The above form entitled *Request for Kidney Transplant Operation* . . . appeared in Wasmuth & Stewart, *Medical and Legal Aspects of Human Organ Transplantation*, 14 CLEV.-MAR. L. REV. 442, 469 (1965).

⁷³ Dr. William Likoff, a Philadelphia transplant pioneer and out-going president of the American College of Cardiology, quoted in N.Y. Times (magazine), April 21, 1968, at 117.

It is to be expected that the number of organs suitable for transplantation will expand as the various sources previously discussed reach their full potential. But it is impossible to believe that these sources will be sufficient to meet the demand within the next few years. Therefore, a means of selecting recipients, a means of determining who shall live and who shall die, must be established. The medical profession is generally opposed to any intervention into their field but in this instance they are simply not qualified to make the decision. At the present time the physician, if he should have to decide who gets the transplant, generally chooses the sickest of those eligible. However, this may not be the best criterion. To say that a man of 85 years with cancer of the stomach in need of a heart should receive one before his 25 year old grandson who has five dependents and no physical defects other than an extremely poor heart is absurd. The physician is simply not trained to make decisions as to the relative merits of who should receive limited transplants. Once again the lawyer should cooperate in establishing committees of qualified persons to make such decisions and in developing criteria on which to base these decisions. These committees are discussed below.

In a 1968 article in the UCLA Law Review, David Sanders, M.D., and Jesse Dukeminier, Jr., Professor of Law at UCLA discussed this problem in the same way that they discussed hemodialysis. Their evaluation of the situation is very comprehensive and will be repeated to a large extent here.⁷⁴

The number of people requiring hemodialysis far exceeds the number actually receiving treatment. Therefore some criteria and method of selection must be chosen. In a few hemodialysis centers a medical evaluation is made, followed by psychiatric, social worth and financial evaluation by a medical committee, a lay committee or a committee composed of both medical and non-medical personnel.

Only physicians licensed to practice medicine in California are authorized to refer patients. The initial contact is with the medical director, who advises the physician concerning the course of action he considers indicated.

If the patient is to be evaluated at the center, referral forms are provided and a date of evaluation set. Transportation costs to the center and costs for evaluation are borne by the patient, his family or by third party payments. Patients found medically suitable for chronic hemodialysis, on original evaluation, are then referred to a Patient Selection Committee composed of physicians, social workers, rehabilitation workers and other specialists as indicated.

The committee then considers the patient from an overall standpoint as to the feasibility of accepting him for the program. Upon selection,

⁷⁴ Sanders & Dukeminier, *Medical Advances and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 U.C.L.A. L. REV. 357 (1968) [hereinafter cited as *Medical Advances*].

a plan of payment for services is arranged and chronic hemodialysis is initiated.⁷⁵

Of the psychiatric evaluation, cooperation is the most important characteristic in that the patient, to recover, must adjust to a new diet, must expect some complications and reversals, and must adjust to a dependence on the machine as well as the stress and strain of being saved twice a week.⁷⁶

The Seattle Artificial Kidney Center at the University of Washington bases its decisions upon an evaluation of the candidate by an anonymous committee which determines the social worth of the candidate.

Dr. Belding H. Scribner, of the University of Washington in Seattle supports the idea of weeding out candidates by a civilian board in order to represent the community and assure that choices are made effectively, without outside pressure.

All candidates for treatment must be under 40 years of age. They must be self supporting and residents of the State of Washington. A first panel, composed of physicians eliminates the medically unfit.

The second panel consists of . . . a clergyman, a housewife, a banker, a labor leader and two physicians. This group makes the final decision, and they remain anonymous in order to be protected from public pressures.

This civilian group bases its decisions on social and economic criteria. Other factors equal, the group chooses those with dependents. It favors patients who are stable in their behavior and appear to be emotionally mature. To have a record of public service is a help—scout leader, Sunday school teacher, Red Cross volunteer. They frown on those who have a record of skipping appointments.⁷⁷

In the San Francisco General Hospital the general criteria "are medical data indicating that the patient is suitable to this treatment and vocational data indicating that the patient can be effectively rehabilitated with the treatment. Other social values must not influence the decision."⁷⁸ The Los Angeles Center uses a different system for selection of candidates to receive hemodialysis:

The patient's medical, psychiatric and sociologic history [are] reviewed and the patient [is] judged to be either an optimum or alternate candidate largely on the basis of medical findings.

An optimum candidate is a patient who is disabled because of chronic renal insufficiency and who does not have any other disabling illness or significant organ involvement. Patients who have cerebrovascular acci-

⁷⁵ Breslow, Public Health Report, Calif. Med. 360 (1967) quoted in *Medical Advances* at 367.

⁷⁶ *Id.* at 368-369.

⁷⁷ REDBOOK, Nov. 1967 at 132-33.

⁷⁸ *Northern California Chronic Hemodialysis Center, Procedure for Selection of Patients for Chronic Hemodialysis Therapy*, 2 (mimeograph 1967), quoted in 15 U.C.L.A. L. Rev. 267, 372 (1968).

dents with paralyzes, severe coronary artery disease and heart failure, another disabling systemic disease or who show unwillingness to cooperate with the prescribed hemodialysis program are examples of alternate candidates. Each time an opening occurs on the program, all referrals [are] classified into one or the other category. The group of optimum candidates will be pooled and one of them will be selected by lot for therapy. If there are no optimum candidates, then the alternate pool will be used to draw the patient for treatment.⁷⁹

The selection process on the basis of social worth, as typified by the Seattle Center's process of selection, has not yet been tested by law. But this is an area in which grave constitutional errors may be committed. Many of the hospitals performing organ transplants are either state supported or perform the work through support from Federal grants. In this day it is certainly not inconceivable that equal protection objectives could be raised if certain age or racial groups were discriminated against. In the selection processes discussed above no definitive standards have been articulated. For this reason there may be constitutional objections on the basis of procedural due process. The answer may be in establishing criteria of social worth but this has not yet proved successful, if it has even been done. The problem with determining social worth is that no one is at present able to make an objective determination of the relative merits of characteristics of personality, dependence and past accomplishments without personal biases and prejudices entering the picture—perhaps unnoticed.

For instance, how can the following persons and personalities be ranked when there is just one organ available: President Eisenhower, Edward Kennedy, O. J. Simpson, an inmate at the Ohio State Penitentiary, a hard working citizen who is the father of three, Elizabeth Taylor, Billy Graham, The Pope, Rap Brown, Pat Nixon. Inherent in such a list is that any one of these persons might be chosen if the right standards and selection committee were used. That is, almost everyone has some social worth to somebody. Such a decision is almost impossible until standards have been perfected and the selection process is conducted by trained personnel.

One suggested answer is to have physicians and hospital personnel do the evaluating. This system is just as bad as the previous one. To begin with, the physician is no more competent to judge social worth than any other member of society. Second, the medical profession has an obligation to society to act on the basis of experience and education. By stepping outside these boundaries, that faith which the public has developed

⁷⁹ Barbour, Meihaus, Berne Le Orellana, *Los Angeles County General Hospital Renal-Dialysis Center, Operational Plans I*, at 3 (mimeograph 1967), quoted in 15 U.C.L.A. L. Rev. 267, 372 (1968).

in the medical profession may dwindle to the point that the public is not willing to donate organs or undergo transplantations. Then a real dis-service has been done to mankind.

What is the answer? This is difficult and may be some years in the making. It is in this area that lawyers may find themselves best able to help. Just as with today's draft laws, there may be no perfect system but almost any is better than the type currently in use in these West Coast Centers. Again a reference to the draft problem suggests at least one alternative: a lottery. After a medical examination those persons who need a transplant and are in such a state of physical well being that they could survive and lead a normal life in the event of successful transplantation could be placed in a pool and names selected at random. There would be separate pools for different types of transplants and for different genetic construction. Those in the pool at the end of a certain time period—perhaps 6 months—could be re-examined to determine physical well being, and, if satisfactory, thrown back into the pool. The pools would never reach gigantic proportions because of the nature of the illness of the potential recipients. Many would never live long enough to be re-examined, and even if they did, their condition would be so deteriorated that they would no longer be eligible for a transplant.

A second possibility is the old "first-come, first served" idea. Here the potential recipient would be medically examined to determine suitability for transplant. The first recipient who happened to be compatible with the first organ presented for transplantation would get it—assuming that the chances for a successful transplant were still good at the time the organ was available. If the recipient had deteriorated somewhat in his condition he would simply not qualify as a recipient. This is hard but then again no profession has easy decisions to make.

A third system would involve a priority based on criteria not yet formulated. Before too many years go by statistical studies by sociologists will reveal just how social worth can be determined. The only reason why such a study has not yet been completed is because it is difficult, time consuming, expensive and heretofore unnecessary. Now, since there is a need, a system of criteria can be developed which will withstand the constitutional objections previously stated.

At the present time a selection of recipients is necessary only in those situations where a donor dies having willed his organs to an institution or a physician without specifying who the recipient is to be. In all other cases, especially with live donors, the recipient is known and has usually procured the organ source himself. When there is talk of procuring organs the subject eventually shifts to whether or not organs should be paid for. This is not a new question because of the fact that blood donors are often times paid for their donations. But organs are a little different.

There are several conflicting viewpoints on this subject. G. A. Leach has suggested:

that selling one's organs is ethically acceptable (though perhaps not socially desirable). We already pay money to people to face major risks to health and to life, and these payments are deliberate incentives to them to put themselves in a situation which carries a definite risk of death. A much more common situation is that high fees are offered for work which involves pressures on our bodies that are a definite risk to health—the case of business executives for example.⁸⁰

Dr. Jean Hamburger has stated

... [I]t is safer to try to discourage, rather than encourage, donors. Giving money for a kidney would have the opposite effect. Our basic rule must be to avoid any kind of pressure (including financial) on the prospective donor.⁸¹

The fact is that volunteers are getting paid for experimental work done in other fields of medicine and it may well spread to transplantation. Therefore, some definite stand must be taken.

Although the donor has been the subject of discussion, the recipient's financial resources and ability to pay for organs lie at the root of this problem. This ability to pay is one other criteria for determining who is to receive transplants. Although there may be no reason to prevent ill patients from purchasing organs from the recipient's side, there are many reasons for preventing it from the donor's side. A potential recipient of great wealth could exert a tremendous amount of coercive influence on a poor donor with a large family. This is a situation which is morally wrong and should not be promoted for any reason. If it were possible to establish a set price for such organs the objections would not be so great. However, there does not, at the present time, appear to be any method of determining such value.

The same considerations do not apply to payment for cadaveric donors. A donor could sell his organs, conditioned on his death first. This could serve as a type of insurance policy with the payments to be made to the next of kin. Payment could also be made to the donor himself at the time he grants consent. Provisions would have to be made for revocation because it would seem to be contrary to public policy to specifically enforce such a contract. In this type of situation the amount of coercion due to monetary pressure would not be so great because of the fact that the recipient would have to wait some time for the organs and therefore would not be willing to expend quite the same amount of money as for immediate receipt from a live donor.

Once again this is an area where the physician and lawyer must com-

⁸⁰ MEDICAL ETHICS at 35, 36. [Leach is the science correspondent for the *New Statesman* (Penguin Books).]

⁸¹ MEDICAL ETHICS at 37.

bine their talents to work out codes of conduct or legislation appropriately designed to solve the problems. A simple legislative enactment would prevent payment to donors except upon death. It may be necessary. There is also the problem of the donor's survivors being contacted and selling the organs before the death of the donor. A legislative provision stating that such contracts were void unless entered into after the donor's death might help this problem.

V. CONCLUSION

Transplantation has ushered a new era into the field of medicine. To utilize the knowledge gained thus far, medical personnel must find solutions to many moral, medical and legal problems. There is no question but that scientific research will provide the answers to the medical problems; but other disciplines must be called in to provide solutions, or means to solutions, for the other problems which have been presented in the preceding pages. The general public turns to the legal profession whenever it appears that its moral and legal rights are in the process of being violated. The lawyer has been placed in the position of protector of these rights and thus has a position of professional responsibility to these people.

Just what is this responsibility and how does it relate to transplantation and those problems presented earlier? In the field of transplantation there are many competing forces. The surgeon may want to transplant and thus does not have the best interest of the patient at heart; the potential recipient may not have the best interests of the donor at heart; the general public's future welfare may be at odds with the welfare of a particular donor or recipient. How are these conflicting interests to be settled? This is the problem for the lawyer. His obligation runs further than just waiting for tragedy to occur and then attempting a solution in concert with the medical profession; he must actively define the interests involved and pose solutions which will be available to handle the problems as they develop.

In developing these solutions the lawyer must consider the following: The field of transplantation has produced medical results which are desirable if the surgical procedures are carried out properly. Transplantation can continue to develop only as long as the general public has confidence in it. Transplantation is a new and experimental field which the general public does not readily understand. Transplantation will continue to develop as a life saving technique only as long as the general public has trust and confidence in the surgeons and allied medical personnel performing the operation. Should the general public lose confidence in the physicians and their transplantation surgery, the general public will no longer donate organs and submit to these experimental

procedures. If transplantation ceases, the general public and future generations will suffer in that countless numbers of people will die unnecessarily.

It is the professional responsibility of the lawyer to see to it that experimental transplantation continues to develop and expand so that lives may be saved and, at the same time, protect the rights of members of the public so that they are treated as human beings and not guinea pigs for experimental procedures. A solution to this problem is dependent upon two principles. First, there must be a full disclosure to those involved so that their consent may be knowing, intelligent, and voluntary. It is for this reason that certain limitations, such as minimum age, maximum age, and health standards must exist. Second, there should be an adversary system set up in the medical profession. Such a system is envisioned in the Uniform Anatomical Gift Act and has a great deal of merit. Such a system would require that the various aspects of transplantation and medicine have different physicians performing the functions. These physicians would have opposing goals. The example pointed out earlier is in the case of a dying man whose organs may be valuable to someone else. The transplant surgeon may want him declared dead as soon as possible, but the attending physician, who has no interest in the transplantation itself, wants his patient to recover. These competing interests should be resolved to insure that the donor gets the benefit of all available medical treatment.

The reason for such a system does not lie in the fact the medical personnel are immoral or unethical. It lies in the fact that the general public wants insurance that its rights are being protected and that the doctor and lawyer can say, "here is our system, see how it protects you". Although the medical profession might oppose such a system at first, a little consideration leads to the conclusion that it may increase public confidence and result in increased transplantation.

The big question, of course, is one of implementation. The easiest method is legislation, and perhaps it is the only method. Legislatures should not try to enter into the field of medicine by telling physicians and hospitals how to operate, transplant, define death, and choose recipients for transplant operations. However, legislatures could force hospitals and medical staffs to adopt standards for each of these areas. It could also be provided that doctors who conform to these standards are absolved from civil liability. Standards such as these could be shown to the donor and recipient in order to prove that their rights were protected. A strict compliance with the standards would allow a doctor to know what his medical responsibilities are and what his legal liabilities would be if he violated these standards.

Many of the problems presented are not susceptible to an immediate

answer for the reasons that the parameters of the problem are not yet solidified. Animal donors and artificial organs are just beginning to create problems and shall continue to do so. In five years problems which we know now may no longer be present or may have been solved. But others will present themselves. The lawyers active in this area must anticipate these problems and attempt to minimize the adverse effects. They must provide a system which allows the physicians to undertake controlled experimentation in order to help man in the future and yet protect the rights of those men who necessarily must be subjected to such experimentation—this is the lawyer's professional responsibility.